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Refined Olive Oil

General Notices

(Ph. Eur. monograph 1456)

Ph Eur

DEFINITION

Fatty oil obtained by refining of crude olive oil, obtained by cold expression or other suitable mechanical means from the ripe drupes of *Olea europaea* L. A suitable antioxidant may be added.

CHARACTERS

Appearance

Clear, colourless or greenish-yellow transparent liquid.

Solubility

Practically insoluble in ethanol (96 per cent), miscible with light petroleum (bp: 50-70 °C).

When cooled, it begins to become cloudy at 10 °C and becomes a butter-like mass at about 0 °C.

Relative density

About 0.913.

IDENTIFICATION

First identification: A, C.

Second identification: A, B.

A. Acid value (see Tests).
B. Identification of fatty oils by thin-layer chromatography (2.3.2).

Results The chromatogram obtained is similar to the corresponding chromatogram shown in Figure 2.3.2.-1. For certain types of olive oil, the difference in the size of spots E and F is less pronounced than in the corresponding chromatogram shown in Figure 2.3.2.-1.

C. Composition of fatty acids (see Tests).

TESTS

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Specific absorbance (*2.2.25*)

Maximum 1.20, determined at the absorption maximum at 270 nm.

To 1.00 g add *cyclohexane R* and dilute to 100.0 mL with the same solvent.

Acid value (*2.5.1*)

Maximum 0.3, determined on 10.0 g.

Peroxide value (*2.5.5, Method A*)

Maximum 10.0, or maximum 5.0 if intended for use in the manufacture of parenteral preparations.

Unsaponifiable matter

Maximum 1.5 per cent.

Place 5.0 g (*m* g) in a 150 mL flask fitted with a reflux condenser. Add 50 mL of *2 M alcoholic potassium hydroxide R* and heat on a water-bath for 1 h, shaking frequently. Add 50 mL of *water R* through the top of the condenser, shake, allow to cool and transfer the contents of the flask to a separating funnel. Rinse the flask with several portions totalling 50 mL of *light petroleum R1* and add the rinsings to the separating funnel. Shake vigorously for 1 min. Allow to separate and transfer the aqueous layer to a 2nd separating funnel. If an emulsion forms, add small quantities of *ethanol (96 per cent) R* or a concentrated solution of *potassium hydroxide R*. Shake the aqueous layer with 2 quantities, each of 50 mL, of *light petroleum R1*. Combine the light petroleum layers in a 3rd separating funnel and wash with 3 quantities, each of 50 mL, of *ethanol (50 per cent V/V) R*. Transfer the light petroleum layer to a tared 250 mL flask. Rinse the separating funnel with small quantities of *light petroleum R1* and add to the flask. Evaporate the light petroleum on a water-bath and dry the residue at 100-105 °C for 15 min, keeping the flask horizontal. Allow to cool in a desiccator and weigh (*a* g). Repeat the drying for successive periods of 15 min until the loss of mass between 2 successive weighings does not exceed 0.1 per cent. Dissolve the residue in 20 mL of *ethanol (96 per cent) R*, previously neutralised to 0.1 mL of *bromophenol blue solution R*. If necessary, titrate with *0.1 M hydrochloric acid* (*b* mL).

Calculate the percentage content of unsaponifiable matter using the following expression:

$$\frac{\quad}{\quad}$$

If 0.032*b* is greater than 5 per cent of *a*, the test is not valid and must be repeated.

Alkaline impurities (*2.4.19*)

It complies with the test.

Composition of fatty acids (*2.4.22, Method A*)

Use the mixture of calibrating substances in Table 2.4.22.-3.

Composition of the fatty-acid fraction of the oil:

— *saturated fatty acids of chain length less than* C_{16}: maximum 0.1 per cent;

— *palmitic acid*: 7.5 per cent to 20.0 per cent;

— *palmitoleic acid*: maximum 3.5 per cent;

— *stearic acid*: 0.5 per cent to 5.0 per cent;

— *oleic acid and isomer*: 56.0 per cent to 85.0 per cent;

— *linoleic acid*: 3.5 per cent to 20.0 per cent;

— *linolenic acid*: maximum 1.2 per cent;

— *arachidic acid*: maximum 0.7 per cent;

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— *eicosenoic acid*: maximum 0.4 per cent;

— *behenic acid*: maximum 0.2 per cent;

— *lignoceric acid*: maximum 0.2 per cent.

Sterols (*2.4.23, Method B*)

Composition of the sterol fraction of the oil:

— *cholesterol*: maximum 0.5 per cent;

— *campesterol*: maximum 4.0 per cent;

— *Δ7-stigmastenol*: maximum 0.5 per cent;

— *sum of contents of Δ5,23-stigmastadienol, clerosterol, β-sitosterol, sitostanol, Δ5-avenasterol and Δ5,24-stigmastadienol*: minimum 93.0 per cent.

The content of stigmasterol is not greater than that of campesterol.

Sesame oil

In a ground-glass-stoppered cylinder shake 10 mL for about 1 min with a mixture of 0.5 mL of a 0.35 per cent *V/V* solution of furfural R in *acetic anhydride R* and 4.5 mL of *acetic anhydride R*. Filter through a filter paper impregnated with *acetic anhydride R*. To the filtrate add 0.2 mL of *sulfuric acid R*. No bluish-green colour develops.

Water (*2.5.32*)

Maximum 0.1 per cent, determined on 1.00 g.

STORAGE

In a well-filled container, protected from light, at a temperature not exceeding 25 °C. If intended for use in the manufacture of parenteral preparations, store under an inert gas.

LABELLING

The label states, where applicable, that the substance is suitable for use in the manufacture of parenteral preparations and the name of the inert gas.

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